



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|------------------------|-------------|----------------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/532,351 | 09/14/2005 | Catharina Everdina Hissink | 05032-00100 | 9053 |
| 22910 | 7590 | 01/05/2009 | | EXAMINER |
| BANNER & WITCOFF, LTD. | | | SU, SUSAN SHAN | |
| 28 STATE STREET | | | ART UNIT | PAPER NUMBER |
| 28th FLOOR | | | 3761 | |
| BOSTON, MA 02109-9601 | | | | |
| | | MAIL DATE | DELIVERY MODE | |
| | | 01/05/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/532,351 | HISSINK ET AL. |
| | Examiner SUSAN SU | Art Unit 3761 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 07 October 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) 8-26 and 36 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7, 27-35, & 37-40 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 14 September 2005 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08) _____
Paper No(s)/Mail Date 14 September 2005

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the election of species in the reply filed on October 7, 2008 is acknowledged. The traversal is on the ground(s) that the subject matter of the claims is interrelated in that a search of all species would not burdensome. This is not found persuasive because no single general inventive concept exists among the specific biodegradable polymers, thus the requirement for searching additional species would pose a serious burden on the Examiner.

Upon further inspection, it is noted that Claims 8-13, which were deemed by the Applicant to be readable on the elected species of lactide polyester, are not wholly dedicated to the species (they are also claiming polyester-carbonate and polyanhydride, which are non-elected species) and are therefore withdrawn from examination by the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Status

Claims 1-40 are pending, of which Claims 8-26 and 36 are withdrawn by the Examiner for being drawn to non-elected species. Claims 1-7, 27-35, and 37-40 are examined on the merits.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 7, 27, 30, 34, 39, & 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to Claims 6-7 & 34, it is held that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation of lactide content of 20-75 mol %, and the claim also recites 55-70 mol % and then 62-69 mol %, which are the narrower statement of the range. Similarly, claim 7 recites the broad recitation of L-enantiomer or D-enantiomer fraction of 65-95 mol %, and the claim

also recites 70-90 mol % and then 85 mol %, which are the narrower statement of the range.

Regarding claim 27, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding Claim 30, the term "particularly" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Regarding Claim 34, the term "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Regarding 39, it appears that the Applicant is trying to recite a Markush group. However, the style of claiming is improper. It is suggested that the Applicant use the acceptable Markush language as outlined in MPEP § 2173.05(d). For example, "using at least one of" should be changed to --using at least one of a form of attachment selected from the group consisting of--.

Claim 40 provides for the use of the drain, but, since the claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 40 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 28, 32, & 37 are rejected under 35 U.S.C. 102(b) for being anticipated by Hahn et al (US 5,129,889, "Hahn").

With regard to Claims 1 & 3-4, Hahn teaches a drain (an epidural catheter is certainly capable of acting as a drain) suitable for draining a human or animal antrum, organ or tissue, characterized in that it comprises an elastic biocompatible, biodegradable synthetic polymer, which polymer has at least one softening point (glass transition temperature) of at most mammalian body temperature. Hahn teaches that the drain comprises polymer such as polylactides, polyglycolides, and polybutyrates (Col. 4 lines 3-20). The Applicant's claim language that draws to the softening point of the polymer is held to be a material property of lactide polyester (polylactides). See MPEP 2112.01 I. Therefore the burden shifts to the Applicant to show that the claimed device and the prior art are not substantially identical.

With regard to Claim 2, Hahn also teaches that the drain essentially entirely consists of said synthetic biodegradable polymer.

With regard to Claim 5, since polyether is optional, it is not given patentable weight in the instant claim.

With regard to Claim 28, Hahn also teaches that the drain is provided with perforations (Col. 4 lines 63).

With regard to Claim 32, Hahn also teaches that the outer diameter of the drain is 0.5 to 50mm (see Claim 1 of Hahn).

With regard to Claim 37, Hahn teaches a method comprising introducing (see Fig. 3) a drain according to claim 1 in said antrum, organ or tissue, such that said antrum, organ or tissue is connected with the environment or another location within the body, after which said drain degrades over time (Col. 4 lines 25-30) and degradation products of said drain are cleared through the digestive channel and/or said antrum, organ or tissue and/or absorbed (Col. 4 line 21) and subsequently metabolized and/or secreted by the body. The language of "treating a disorder associated with dysfunction of natural drainage of body fluids from an antrum, organ or tissue" is in the preamble and is held to be functional language and therefore not given patentable weight.

7. Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hahn.

Claim 35 is a product-by-process claim. As explained in the MPEP, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the

instant case, the drain as defined in Claim 1 has been shown to be the same as that of prior art. Although a process of production for the drain has not been disclosed by Hahn (and therefore may be different from that claimed by the Applicant), the burden now shifts to the Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 6-7, 30-31, & 38- 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn.

With regard to Claims 6-7, Hahn teaches that the polyester is a lactide-caprolactone copolyester (Col. 4 lines 9-11). It would require only routine skills in the art to modify Hahn so that the lactide content is 20-75 mol %. It has been held that

where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (see MPEP 2144.05 II). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of obtaining a polymer that has a desirable structural property and absorbility.

With regard to Claims 30-31, Hahn does not expressly teach the length or thickness of the drain. However, it would require only routine skills in the art to find the optimal length and thickness of the drain so that fluids can be properly drained outside the body and there is large enough of a conduit for the fluids to flow through while the drain is thick enough to withstand the compression from the surrounding body tissues. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of making a drain that would have the right structures for draining fluids out of a patient.

With regard to Claim 38, Hahn does not explicitly teach that the disorder is selected from (chronic) sinusitis, inflammation of the middle ear, liver disorders, disorders of the gastro-intestinal tract, tear duct disorder, surgical wound drainage, and thoracic disorder. However, it would require only routine skills in the art to apply a biodegradable tubular member as taught by Hahn into other medical arts such as would drains and for treating inflammation of the middle ear since it is well known that tubular conduits allow for transport of fluids (which allows for delivery of medicament or removal of pus and such). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of using a biodegradable tube in

medical applications so that the tube can be left in the tissue or orifice for an extended period of time.

With regard to Claim 39, Hahn does not expressly teach that the drain is introduced using at least one of an attachment selected from the group consisting of sealant, suture, and staple. However, it is general knowledge in the art that drains have been anchored in the body by sutures (see Kettenbach, US 6,406,691, Col. 1 line 55 and Col. 2 line 1 for the general level of knowledge in the art). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn for the purpose of preventing the drain from being dislodged inadvertently.

With regard to Claim 40, Hahn also teaches that the drain is used for preparing a kit (e.g. the package shown in Fig. 2) but does not expressly teach that it is for the treatment of a disorder associated with dysfunction of natural drainage of body fluids from an antrum, organ or tissue. However, the language does not contribute to the steps of a claimed method or the structure of the drain/kit. The claimed language is therefore held to be functional language and not given patentable weight. Furthermore, the drain of Hahn is fully capable of being used for treatment of dysfunction of natural drainage as deemed appropriate by the practitioner.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Jackson et al. (US 2003/0134811, "Jackson"). Hahn does not expressly teach that the polymer is loaded with radiopaque fillers or pharmaceutical components. Jackson teaches a polymer for making a nasal stent that has anti-inflammatory agents mixed into the biodegradable polymer. It would have been obvious to one of ordinary

skill in the art at the time of the invention to modify Hahn with Jackson for the purpose of preventing medical complications after implanting the drain into the patient.

12. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Noda (US 6,669,711). Hahn does not expressly teach that the drain is a nasal drain. Noda teaches a nasal drain made of polymeric material. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn with Noda for the purpose of adapting the drain for multiple medical purposes.

13. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Goldsmith, III (US 5,026,378, "Goldsmith").

Regarding Claim 33, Hahn does not expressly teach a funnel shaped element on at least one end. Goldsmith teaches a drain with a funnel shaped element on at least one end (see Claim 1 of Goldsmith). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn with Goldsmith for the purpose of keeping the drain stably lodged in the body cavity for proper drainage of fluids.

Regarding Claim 34, Hahn and Goldsmith do not expressly teach that the funnel has a length of 2-20mm and a funnel diameter of 3-30mm. However, adjusting the size of a drain and the funnel that keeps the drain inside a body passage would require only routine skills in the art. Furthermore, the size of the drain and the funnel would need to be adjusted based on the patient for optimal comfort. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hahn and Goldsmith for the purpose of making the drain fit.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761